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ATTORNEY'S DOCKET NUMBER 06270/HG TRANSMITTAL LETTER TO THE UNITED STATES **DESIGNATED/ELECTED OFFICE (DO/EO/US)**

CONCERNING A SUBMISSION UNDER 35 U.S.C. 371

U.S. APRILICATION NO (IS known asee 67 CFR 1.5)

| I IIVI ERIVA | PCT/JP2004/016063 | 22 OCTOBER 2004 | 24 OCTOBER 2003 | | | | | | | |
|---|--|---|-----------------|--|--|--|--|--|--|--|
| TITLE OF INVENTION THERAPEUTIC AGENT FOR KERATOCONJUNCTIVAL DISORDER | | | | | | | | | | |
| APPLICANT(S) FOR DO/EO/US | | | | | | | | | | |
| Masatsugu NAKAMURA; and Shin-ichiro HIRAI Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information: | | | | | | | | | | |
| 1. X This is a FIRST submission of items concerning a submission under 35 U.S.C. 371. | | | | | | | | | | |
| 2. | This is a SECOND or SUBSEQUENT submission of items concerning a submission under 35 U.S.C. 371. | | | | | | | | | |
| 3. X | This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items | | | | | | | | | |
| | (5), (6), (9) and (21) indicated below. | | | | | | | | | |
| 4. LXI | The US has been elected (Article 31). | | | | | | | | | |
| 5. X | A copy of the International Application as filed (35 U.S.C. 371(c)(2)) | | | | | | | | | |
| | a. is attached hereto (required only if not communicated by the International Bureau). | | | | | | | | | |
| | b. X has been communicated by the International Bureau. | | | | | | | | | |
| | c. Is not required, as the application was filed in the United States Receiving Office (RO/US). | | | | | | | | | |
| 6. X | An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)). | | | | | | | | | |
| | a. 🔀 is attached hereto | | | | | | | | | |
| | b. has been previously submitted under 35 U.S.C. 154(d)(4). | | | | | | | | | |
| 7. | Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)) | | | | | | | | | |
| | a. are attached hereto (required only if not communicated by the International Bureau). | | | | | | | | | |
| | b. have been communicated by the International Bureau. | | | | | | | | | |
| | c. have not been made; however, the time limit for making such amendments has NOT expired. | | | | | | | | | |
| | d. have not been made and will not be made. | | | | | | | | | |
| 8. 🗆 | An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)). | | | | | | | | | |
| 9. X | An eath or declaration of the Inventor(s) (35 U.S.C. 371(c)(4)). | | | | | | | | | |
| 10. 🗌 | An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)). | | | | | | | | | |
| Items | s 11 to 20 below concern document(s | i) or information included: | | | | | | | | |
| 11. 🔲 | An Information Disclosure Statement | under 37 CFR 1.97 and 1.98. | | | | | | | | |
| 12. 🛚 | An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included. | | | | | | | | | |
| 13. X | A preliminary amendment. | | | | | | | | | |
| 14. | An Application Data Sheet under 37 CFR 1.76. | | | | | | | | | |
| 15. | A substitute specification. | | | | | | | | | |
| 16. X | A power of attorney and/or change of address letter. | | | | | | | | | |
| 17. | A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821-1.825. | | | | | | | | | |
| 18. 🗔 | A second copy of the published International Application under 35 U.S.C. 154(d)(4). | | | | | | | | | |
| 19. | A second copy of the English language translation of the International application under 35 U.S.C. 154(d)(4). | | | | | | | | | |
| 20. 🗶 | Other items or Information: | Express Mall Label No. EV 842 Date of Deposit: April 20, 2006 | 303 211 US | | | | | | | |

Copy of: (i) NOTIFICATION PCT/IB/304; (ii) SECOND AND SUPPLEMENTARY NOTICE PCT/IB/308; (iii) NOTIFICATION PCT/IB/301; (iv) NOTIFICATION PCT/IBJ311; (v) WO 2005/039574 A1 (title page only), the publication of PCT/JP2004/016063; (vi) English language INT. SEARCH REPORT; and (vii) REQUEST FOR PUBLICATION OF ASSIGNMENT INFORMATION.

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Date of Deposit: April 20, 2006
I hereby certify that this paper is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above with sufficient postage, and is addressed to the Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria VA 22313.1450

IAP15 Rec'd PCT/PTO 2 0 APR 2006

PTO-1390 (Rev. 02-2005)
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| | ON NO. (if known | , see 37 CFR 1. | 5) INTERNATIONAL A | APPLICATION NO. | ATTORNEY'S DOC | KET NUMBER | | | | |
|---|---|------------------------|---|------------------|-----------------------|------------|--|--|--|--|
| 1 10 | 10/576719 PCT/JP2004/016063 | | | | 06270/HG | | | | | |
| The folio | owing fees have b | CALCULATIONS | PTO USE ONLY | | | | | | | |
| 21. 🙀 Basid | c national fee | | ••••••••••• | \$300 | \$ 300.00 | | | | | |
| 22. X Exam If International pr PCT Article 33 | ination fee reliminary examina (1)-(4) | \$ 200.00 | | | | | | | | |
| 23. X Sean Search fee (37 Cl Internation International Sea | ch fee FR 1.445(a)(2)) ha nal Searching Aut rch Report prepar s | \$ 400.00 | | | | | | | | |
| | TOTAL OF 21, 22 | \$ 900.00 | | | | | | | | |
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| *************************************** | | : | TOTAL | FEES ENCLOSED = | \$ 940.00 | | | | | |
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| b. Please charge my Deposit Account No in the amount of \$ to cover the above fees. A duplicate copy of this sheet is enclosed. | | | | | | | | | | |
| c. X The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 06-1378. A duplicate copy of this sheet is enclosed. | | | | | | | | | | |
| d. X Fees are to be charged to a credit card. WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038. | | | | | | | | | | |
| NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been mat, a petition to revive (37 CFR 1.437(a) or (b)) must be filled and granted to restore the international Application to pending status. | | | | | | | | | | |
| SEND ALL CORRESPONDENCE TO: | | | | | | | | | | |
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

(U.S. National Phase Appln. Appl. No.

based on PCT/JP2004/016063)

Masatsugu NAKAMURA et al Applicant

Filed Concomitantly herewith

For THERAPEUTIC AGENT FOR

KERATOCONJUNCTIVAL DISORDER

Docket No. 06270/HG

Customer No.: 01933

REQUEST FOR PUBLICATION OF ASSIGNMENT INFORMATION

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

SIR:

No.: EV 842 303 211 US Date of Deposit: April 20, 2006 I hereby certify that this paper is being deposited with the United States Postal

Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 23313-1450.

Lori Valdes

In the event that this Paper is late filed, and the necessary petition for extension of time is not filed concurrently herewith, please consider this as a Petition for the requisite extension of time, and to the extent not tendered by credit card payment, authorization to charge the extension fee, or any other fee required in connection with this Paper to Account No. 06-1378.

It is requested that the following assignment information be published as part of the 18-month publication of the present application:

> SANTEN PHARMACEUTICAL CO., LTD. 9-19, Shimoshinjo 3-chome, Higashiyodogawa-ku Osaka-shi, Osaka 533-8651 Japan

> > Respectfully submitted,

Frishauf, Holtz, Goodman & Chick, P.C. 220 Fifth Ave., 16th floor New York, NY 10001-7708

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HG/lpv

⊉ŔBERT**⁴** GOODMAN

Æeg. No. 17,081